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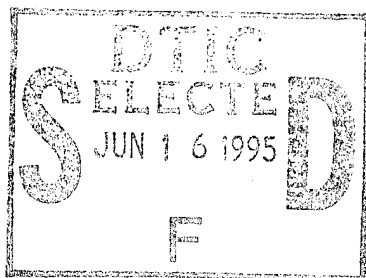


ARMSTRONG

TESTING AND EVALUATION OF THE
OMNI-TECH MEDICAL, INC.
OMNI-VENT, SERIES D MRI VENTILATOR

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Final Technical Report for Period July 1993 - April 1994

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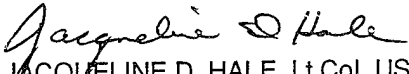
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The Office of Public Affairs has reviewed this report, and it is releasable to the National Technical Information Service, where it will be available to the general public, including foreign nationals.

This report has been reviewed and is approved for publication.


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TABLE OF CONTENTS

BACKGROUND	1
DESCRIPTION	1
METHODS	2
Baseline Performance Assessment	4
Vibration	4
Environmental	5
Altitude	6
Rapid Decompression	6
Airborne Feasibility	6
RESULTS	7
Baseline Performance Assessment	7
Vibration	7
Environmental	7
Altitude	7
Rapid Decompression	8
Airborne Feasibility	9
RECOMMENDATIONS	11
ACKNOWLEDGMENTS	11
REFERENCES	12
APPENDIX A	13

LIST OF FIGURES

Fig No.	
1.	The OMNI-VENT, Series D MRI Ventilator, and accessories.....2
2.	The Omni-Vent connected to a Bird oxygen blender.....3
3.	Omni-Vent secured to vent holder.....5
4.	Tidal Volume during altitude testing.6
5.	Peak airway pressure during altitude testing.....7
6.	Omni-Vent secured to a Horton Bracket on a C-130/141 stanchion pole...10
7.	Omni-Vent secured to a Horton Bracket on a C-9A cantilever arm.....10
8.	Omni-Vent mounted on a Bird Sled with D cylinder holder.....11

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TESTING AND EVALUATION OF THE OMNI-TECH MEDICAL, INC. OMNI-VENT, SERIES D MRI VENTILATOR

BACKGROUND

Evaluation was requested by Omni-Tech Medical, Inc. to verify that the Omni-Vent Series D MRI Ventilator, hereinafter called the Omni-Vent, meets requirements for use in the aeromedical evacuation system. The Omni-Vent is already in use in DOD medical facilities and civilian air/mobile centers, and has potential to accommodate a patient manifested for USAF aeromedical evacuation.

DESCRIPTION

The Omni-Vent is a pneumatically powered, single circuit, volume-constant, time-cycled and flow-variable ventilator (Fig 1). This ventilator utilizes a high-pressure drive with high internal resistance to control pressure and is considered a non-constant pressure generator. As such, it produces a flow pattern that is constant in spite of changes in lung mechanics (inspiratory square wave). The Omni-Vent has quick-connect features that allow the operator to provide for all clinical ventilatory needs: controlled ventilation (CV), continuous-flow intermittent mandatory ventilation (IMV), constant positive airway pressure (CPAP), high-frequency and jet-ventilation, positive end expiratory pressure (PEEP), and inspiratory to expiratory ratios that are infinitely adjustable to inverse proportions if needed. A pressure-relief valve allows for both the prevention of barotrauma and time-cycled, pressure-relieved ventilation. In standard use, the Omni-Vent may be used in conjunction with a variety of face masks, esophageal obturator airways, cricothyroid tubes, endotracheal and tracheostomy tubes, as well as jet tubes and bronchoscopes. Humidification, air/oxygen blenders and monitor-alarm systems may be incorporated as needed, but will not be tested in conjunction with this unit during evaluation. Size: 10 x 13 x 18 centimeters (4 x 5 x 7 inches). Weight: 2 kgs (4.5 lbs). Case material: aluminum. Gas pressure range: 25 to 140 psi. Tidal volume range: 0 to 1.5 liters. Flow range: 0 to 98 liters per minute. Breaths per minute: 0 to 150. PEEP/CPAP pressure: 0 to 50 cm/H₂O (limited by valve used). Continuous flow: 0 to 60 liters per minute. Internal compliance: 0. Operating temperature range: -45° F to 140° F. Patient Circuit: Custom Omni-Vent disposable tubing circuit, or any circuit where the Bird No. 2575 exhalation valve is used, are the only circuits that will function according to manufacturer's specifications. Pressure relief: 0 to 120 cm/H₂O.

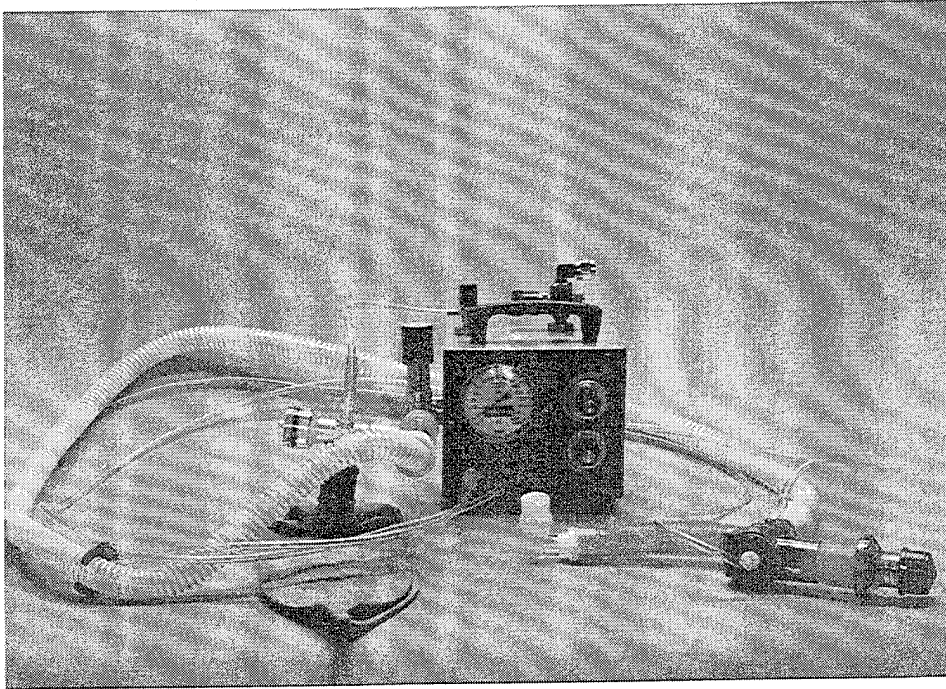


Figure 1. The OMNI-VENT, Series D MRI Ventilator, and accessories.

METHODS

The Aeromedical Research Team developed an airworthiness test matrix incorporating military standards and addressing test procedures covering safety, human factors, environmental and engineering issues of concern to medical equipment items. A Procedures Guide (1) describes all tests in airworthiness assessment that an equipment device might experience during evaluation. Due to unique characteristics of an item, the full set of tests may not be required, i.e., the Omni-Vent did not require electrical safety or electromagnetic interference testing since there are no electrical parts. The following information is derived from the Procedures Guide, and briefly describes the specific tests that are to be performed. Each device is first subjected to a Baseline Performance Assessment (BPA), a test of the operation of the device using directions and procedures described in the operator's manual (2).

Next, various tests are conducted that simulate the environment the device may encounter. We duplicate field storage and operational conditions as closely as possible. The tests are designed to assess one parameter at a time. Comparison to the BPA enables us to assess each test's effect on the item.

Data are collected by computer whenever possible, or recorded manually on specially formatted "Data Collection Sheets."

Test Setup. The BPA was used to validate the function of the Omni-Vent in each of the test conditions. Initial performance was assessed at standard ambient conditions and served as a baseline for later comparison. The Omni-Vent was connected to an Aridyne air compressor and the breathing circuit was connected per the operation manual. The patient end was connected to a Bio-Tek VT-2 ventilator tester. For test purposes the Omni-Vent settings were: Breath rate - 20 per minute; Tidal volume - 1.0L. The VT-2 tester was set with a resistance value of 20; compliance of .05 L/cmH₂O; atmospheric pressure - during ground level testing - 747 mmHg (during altitude testing the VT-2 was reset to correspond to the atmospheric pressure at each test altitude); relative humidity - 50%; and gas temperature - 25° C. When other test settings were used, they were documented in the protocol for that specific test. The VT-2 reads and records the following information: breath rate, inspiratory/expiratory(I:E) ratio, tidal volume, minute volume, inspiratory time, inspiratory hold, expiratory time, expiratory hold, cycle time, peak airway pressure, peak lung pressure, end expiratory pressure, mean airway pressure, inspiratory flow and expiratory flow in the Full Test mode. The Bird Oxygen Blender model 3300 (Fig 2) was attached to the Omni-Vent gas inlet adapter to confirm its compatibility.

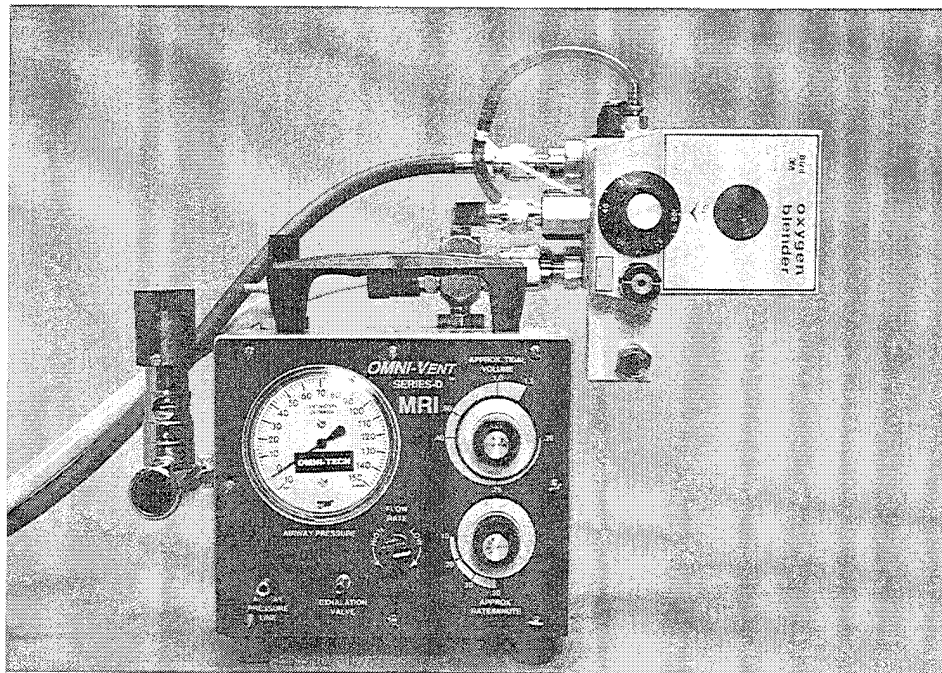


Figure 2. The Omni-Vent connected to a Bird Oxygen Blender.

Performance Check. The Full Test was applied to all phases of testing. Three Full Tests were accomplished prior to starting each laboratory test to document baseline values. A Full Test was conducted at 5-minute intervals to verify ventilator performance, unless otherwise stated in the specific test requirement. A Status Test was also used to monitor the ventilator. This test provides the following updated

information every 2 breaths: breath rate, tidal volume, minute volume, and I:E ratio. During the status test, if any abnormal readings occurred, a Full Test was done.

Baseline Performance Assessment

The purpose of the BPA is to quantitatively measure and record the ventilator's performance under standard ambient conditions before adverse environmental testing. The BPA was used as a reference to measure subsequent performance. It verifies manufacturer's specifications and checks for safe operation before testing. Specifically, the BPA includes the following:

Initial inspection. The initial inspection is an operational verification comparing the ventilator's operating characteristics (e.g., breaths per minute, tidal volume, I:E ratio) to its numerically displayed parameters. These operating characteristics are measured, recorded, and compared to the manufacturer's published specifications.

Vibration

These tests are designed to determine an item's construction, durability, and performance during vibrations that occur on aircraft. The ventilator was subjected to vibration tests in accordance with MIL-STD-810D (3). Tests consist of random (11 to 2,000 Hz) and sinusoidal (5 to 500 Hz) curves on X, Y, and Z axes. During sinusoidal tests, the ventilator was operated and vibrated for 5 sweeps of 15-minute duration (for a total of 75 minutes) on each axis. During random tests, the ventilator was operated and vibrated for 30 minutes on each axis. Before and after each axis, a visual examination of the respirator was performed and VT-2 measurements were recorded.

During vibration testing the Omni-Vent was secured to a segment of a NATO litter using the vent holder (Fig 3) that clamps onto the litter handle.

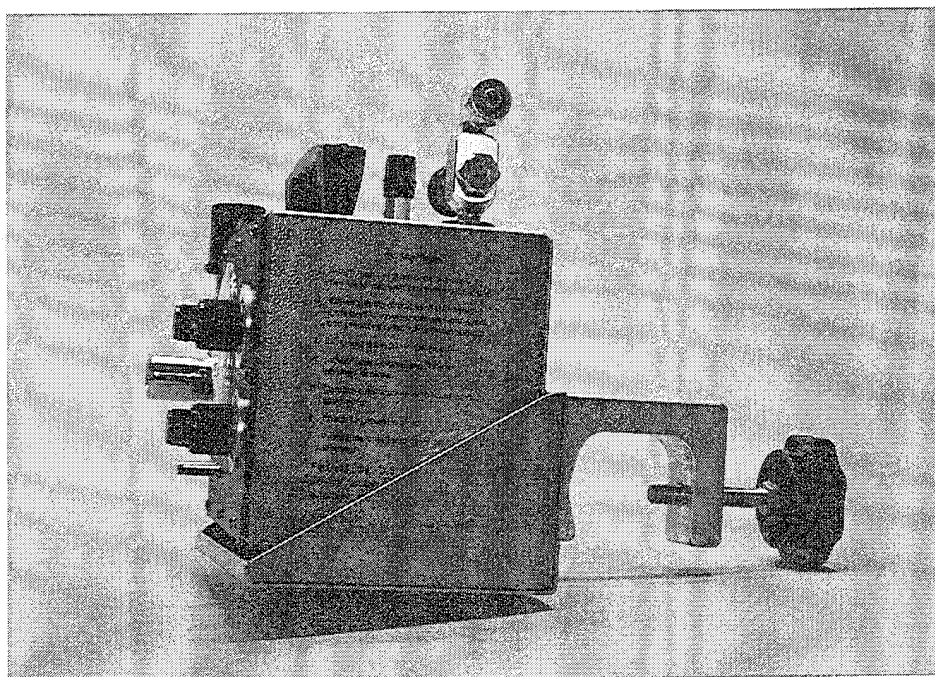


Figure 3. Omni-Vent secured to vent holder.

Environmental

Environmental test conditions are tailored (based on the aeromedical operational environment) from MIL-STD-810D. These tests measure the system's performance under varying temperature and humidity conditions encountered during transport.

The Omni-Vent was placed inside the environmental chamber, the compressor and VT-2 were set up outside the chamber. At the end of each test, the chamber was dehumidified and the temperature adjusted to 24.7° C (75° F) to return it to existing ambient conditions. The ventilator remained inside the chamber for 30 minutes during this post-test stabilization period, then post-test measurements were taken.

Hot Temperature: Operation: 49° C \pm 2° C (120° F \pm 3.6° F) for 2 hours.
 Storage: 60° C \pm 2° C (140° F \pm 3.6° F) for 6 hours.

Cold Temperature: Operation: 0° C \pm 4° C (32° F \pm 7.2° F) for 2 hours.
 Storage: -40° C \pm 2° C (-40° F \pm 3.6° F) for 6 hours.

Humidity: Operation: 94 \pm 4 % relative humidity
 29.5° C \pm 2° C (85° F \pm 3° F) for 4 hours.

Three Full Tests were performed prior to starting, at half-hour intervals, and at the end of the test period. For operational testing, the unit was evaluated in the chamber while operating with the patient tubing coming to the outside of the chamber and connected

to the VT-2. For storage testing the unit was allowed to return to ambient temperature over a 30-minute period, then a post-test assessment was done.

Altitude

The purpose of the altitude chamber test is to approximate the stresses of the airborne environment due to the effects of reduced barometric pressure. The standard protocol is a simulated climb to 10,000 feet (chamber pressure of 522 mmHg) at an ascent rate of 5,000 feet (ft) per minute, stopping at 2,000 ft increments to assess test item operation and compliance with the prescribed operating parameters.

The Omni-Vent was operated while connected to the VT-2 and the VT-2 was reset at each stop to the appropriate pressure for the simulated altitude. The ventilator was given time to stabilize at each 2,000 ft incremental stop, and a full test was recorded.

Rapid Decompression

Although rapid decompressions are uncommon in military transport aircraft, the effect of such an occurrence on a medical item could present a severe safety hazard to the patient, crew, or aircraft operations.

Rapid decompression testing involves ascending to 8,000 feet at a minimum of 5,000 feet per minute. Over periods of 60 seconds, 7 seconds, and 1 second the chamber is decompressed to 40,000 feet to create a decompression. A 60-second decompression would simulate a decompression resulting from a faulty door seal inflight. The 7-second and 1-second decompressions would simulate a decompression resulting from the loss of a door or window inflight. Testing was conducted in the small equipment test chamber. While inside the chamber, the Omni-Vent was connected to a Manley Lung, mechanical lung simulator. The simplified mechanical test lung was used because of the possibility of damage to the sensitive VT-2. Pre- and post-tests were conducted with the VT-2 outside the chamber. The ventilator was observed and allowed to continue to operate, then the chamber was returned to ground level. At ground level, three full tests were recorded.

Airborne Feasibility

The purpose of airborne feasibility assessment is to validate the Omni-Vent's operation and compatibility on USAF aeromedical aircraft. The Omni-Vent could potentially be used to ventilate patients on any one of the following aircraft: C-5, C-9, C-12, C-17, C-21, C-27, C-130, C-141, KC-10, or KC-135. We determined that an evaluation on a C-9 and C-130 would be representative of most aeromedical evacuation missions. On the C-9 aircraft, oxygen was supplied via the therapeutic oxygen system using a Schrader adapter low-pressure hose. On the C-130 oxygen was supplied via D cylinders that were mounted on a NATO litter Bird ventilator sled. Oxygen can also be supplied from the 10 Liter PT Lox. We evaluated the operational capability of the ventilator under actual flight conditions on the C-9 and C-130,

integrated it with aircraft systems, performed on/off load procedures, securing methods, medical crew interface, and other human factor evaluations. Although we did not utilize a helicopter, the Omni-Vent could be utilized on helicopters operated by USAF Air Rescue and Special Operations.

RESULTS

Baseline Performance Assessment

During the initial inspection, we noticed that the tidal volume and breath rate changed from the set values as we varied the flow knob. Actual use of the ventilator will require manual counting of the ventilation rate and the use of a hand-held spirometer to confirm the volume, since the Omni-Vent has only a proximal airway pressure gauge to indicate airway pressure.

Vibration

During evaluation in the X-axis the breath rate, tidal volume, and peak airway pressure were 12% over pretest values. The Omni-Vent operated within 10% of pretest values during the Y and Z axes. The deviations that occurred in the X-axis can be manually compensated for by a respiratory technician or medical attendant. The set screw on the pressure relief valve must be firmly set to ensure no movement during transport. Constant surveillance of the patient and ventilator is essential in order to detect any deviations and make the necessary adjustments.

Environmental

The Omni-Vent operated within 10% of the pretest characteristics during environmental testing with the following exceptions. The unit operated within 18% during hot operation, and within 12% during humidity testing. Following cold storage, the Omni-Vent operated within 10% of pretest values after a 70-minute stabilization period. As stated earlier, a respiratory technician or medical attendant will have to make the appropriate adjustments to compensate for any deviations.

Altitude

Due to barometric pressure changes, the ventilator responded by increasing the tidal volume and peak airway pressure during ascent and by decreasing both values during descent (Figs 4 & 5).

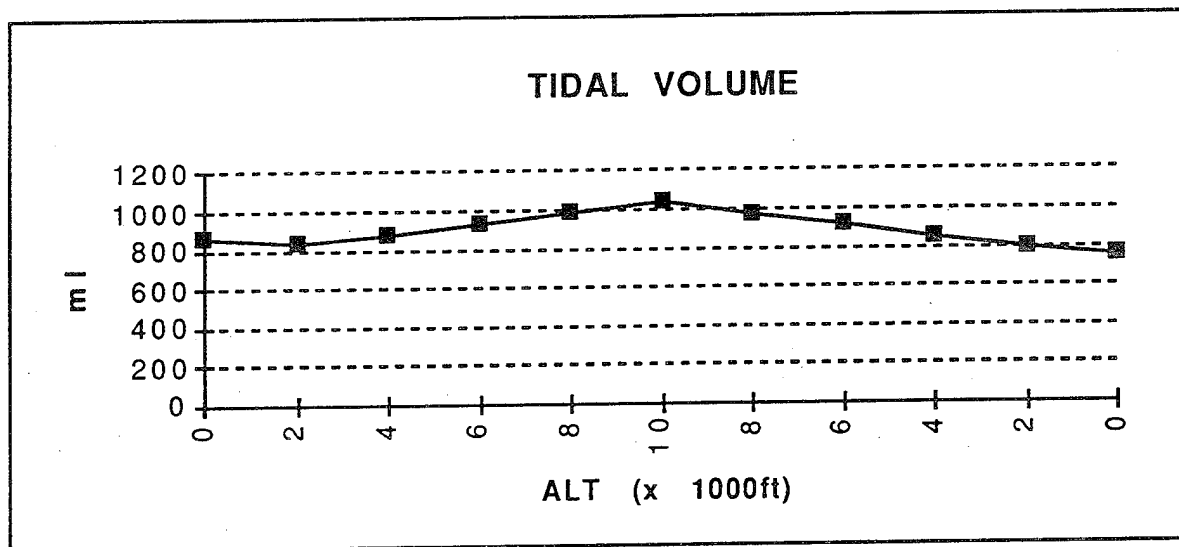


Figure 4. Tidal Volume during altitude testing.

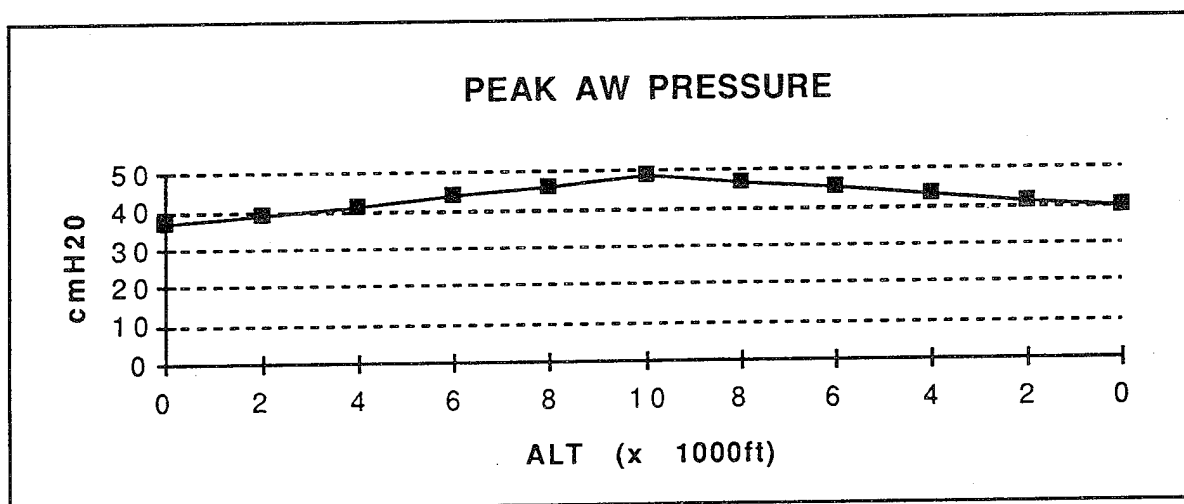


Figure 5. Peak airway pressure during altitude testing.

The PEEP valve did not change the operational characteristics of the Omni-Vent except for the normal effect of the PEEP valve to maintain the positive end expiratory pressure at the preset value.

To compensate for the effects of barometric pressure changes, constant monitoring of the patient and ventilator is essential in order to make necessary adjustments.

Rapid Decompression

For this test, the peak airway pressure was 32 cmH2O, and the pressure relief valve (PRV) was adjusted to relieve pressure in excess of 60 cmH2O from the patient circuit.

During initial decompression testing the ventilator operated during the 60-, 7-, and 1-second decompressions. The PRV failed to relieve excess pressure. Pressure exceeded 140 cmH2O pressure in the patient circuit. This amount of pressure could cause damage to the patient's lungs.

The Omni-Vent was returned to the manufacturer for modification of the PRV. The modification consisted of the installation of two, one-way valves on the two gas outlet ports of the timing valves acrylic block and the unit was returned to Aeromedical Research.

Following the manufacturer's modification of the Omni-Vent, the peak airway pressure was set to 32 cmH2O, and the PRV was adjusted to relieve pressure in excess of 60 cmH2O. During testing, the ventilator operated during the 60-, 7-, and 1-second decompressions. At this setting, the PRV relieved some of the excess pressure during the decompressions that resulted in the following peak airway pressures; 60 Sec: 48-80 cmH2O, 7 Sec: 44-78 cmH2O, and 1 Sec: 46-96 cmH2O. The decompressions did not cause damage to the ventilator and should not present a hazard to the patient or attendant. In an effort to not exceed an airway pressure of 100 cmH2O for an adult patient during a rapid decompression, the PRV should be set to relieve pressure in excess of 60 cmH2O. In the unlikely event of a rapid decompression, the ventilator would require adjustment by the respiratory technician or medical attendant.

Airborne Feasibility

The ventilator operated adequately, was "user friendly," and easy to enplane and deplane. The Omni-Vent vent holder secured easily to the NATO litter handle, Horton Bracket secured to a C-130/C-141 stanchion pole litter bracket (Fig 6), or Horton Bracket secured to a C-9 cantilever arm (Fig 7). In the absence of a vent holder, the Omni-Vent is easily secured to an equipment litter using one litter strap, or secured to a Waters Bracket using the existing bracket straps. In addition to using those securing methods, the ventilator was mounted on a Bird Sled with D cylinder holder (Fig 8) attached to a NATO litter. Since the Omni-Vent could not be secured using the existing securing hooks, one litter strap was used. The Bird Sled facilitated the enplaning of the simulated ventilator patient from the flightline onto the C-130 aircraft during a simulated contingency mission. Once all litter patients were loaded, the Aeromedical Evacuation Crewmember (AECM) could concurrently connect the PT Lox to the cylinder yoke setup, avoiding an interruption in ventilator operation. At altitude, the Omni-Vent required slight changes in the flow to compensate for altitude changes.

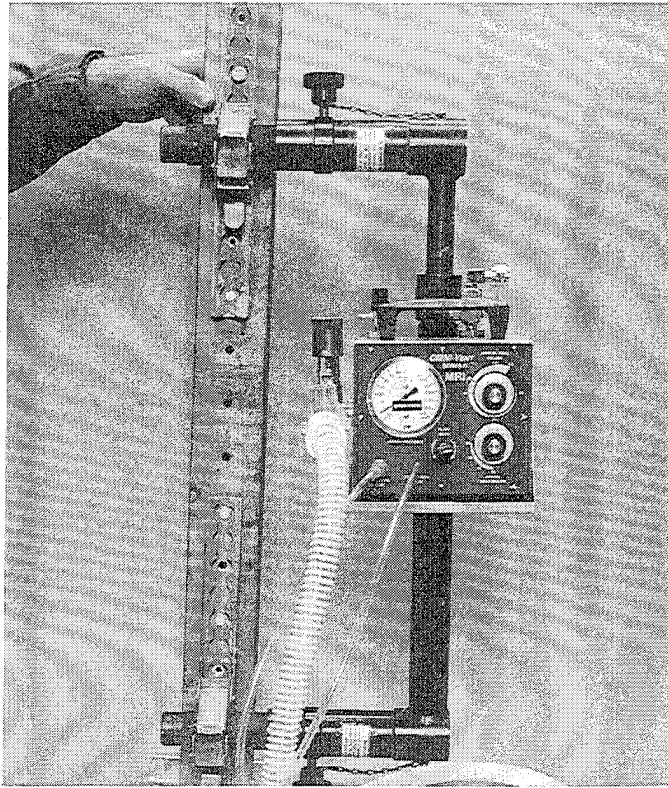


Figure 6. Omni-Vent secured to a Horton Bracket on a C-130/C-141 stanchion pole.

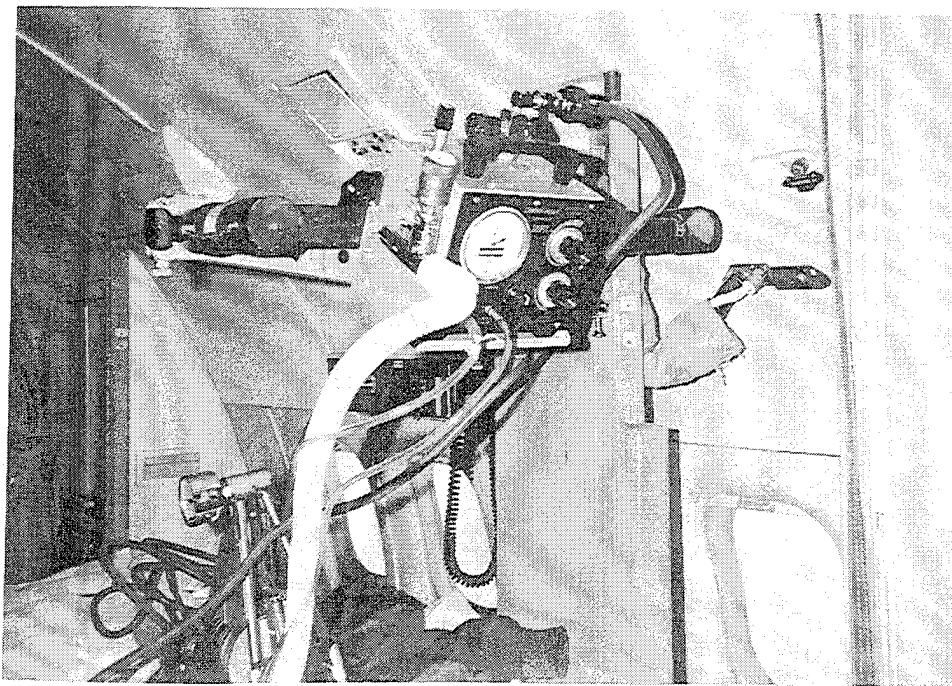


Figure 7. Omni-Vent secured to a Horton Bracket on a C-9A cantilever arm.

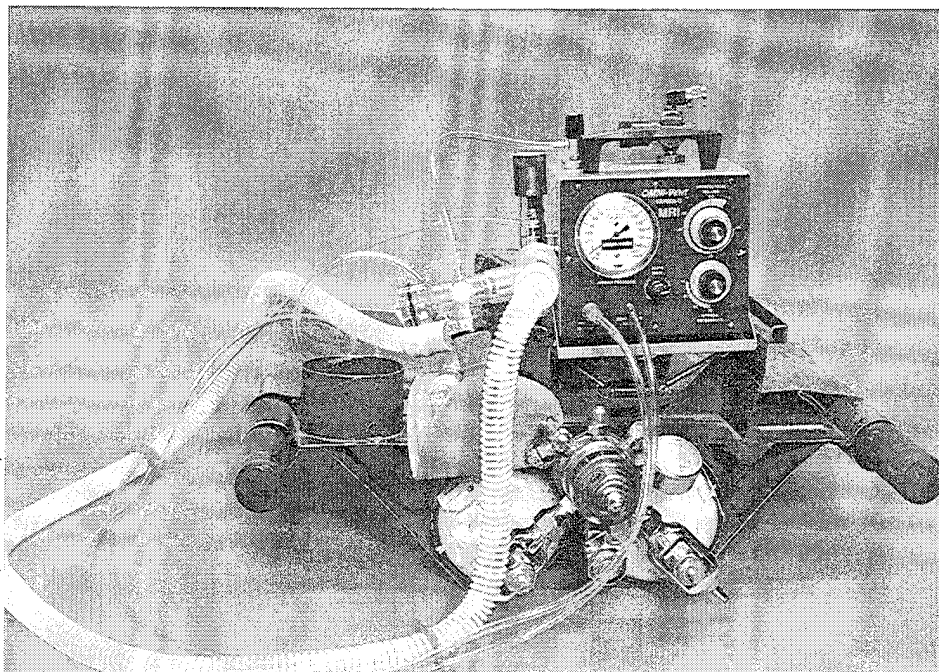


Figure 8. Omni-Vent mounted on a Bird Sled with D cylinder holder.

RECOMMENDATIONS

The Omni-Vent Series D MRI Ventilator is acceptable for inflight use, provided the following requirements are met:

1. Respiratory technician or medical attendant is required to monitor tidal volume and adjust the unit appropriately during all phases of flight.
2. A heat moisture exchanger be used for patient humidification.
3. The approved Omni-Vent has a pressure relief modification. To facilitate the identification of an approved Omni-Vent Series D MRI Ventilator, we recommend that the letters AE be printed after the serial number, e.g., Serial No. 3173AE.
4. Use the custom Omni-Vent disposable tubing circuit, or any circuit where the Bird No. 2575 exhalation valve is used since these are the only circuits that will function properly.
5. Use the Vent Holder with pole clamp to secure to the NATO litter.

ACKNOWLEDGMENTS

I would like to thank the following individuals for their support during the evaluation of the Omni-Vent Series D MRI Ventilator: LtCol Jacqueline Hale, 1Lt Philip Preen, 2Lt Kindra Larson, MSgt Victor Elizondo, TSgt Mary Thomas, TSgt Butch Blake, and the crews from the 32 AEG Kelly AFB and 57 AES Scott AFB, and the USAFSAM/AN staff.

REFERENCES

1. Aeromedical Research Procedure Guide.
2. Omni-Vent Series D MRI Ventilator, Operator's Manual.
3. MIL-STD-810D, Environmental Test Methods and Engineering Guidelines.

APPENDIX A

SPECIFICATIONS AND FUNCTIONAL OPERATIONAL PROCEDURES OF THE OMNI-VENT, SERIES D MRI VENTILATOR

Manufacturer: Omni-Tech Medical, Inc.
6206 SW Terrace
Topeka, Kansas 66615
(913) 273-8915

Dimensions: 4 x 5 x 7 inches
10 x 13 x 18 centimeters

Weight: 4.5 lbs
2 kgs

Case Material: aluminum

Gas Pressure Range: 25 to 140 psi

Tidal Volume Range: 0 to 1.5 liters

Flow Rate Range: 0 to 98 liters per minute

Breaths Per Minute: 0 to 150

PEEP/CPAP Pressure: 0 to 50 cm/H₂O (limited by valve used)

Continuous Flow: 0 to 60 liters per minute

Internal Compliance: 0

Operating Temperature Range: -45° F to +140° F

Exhalation Valves: Custom Omni-Vent Circuit or
Bird No. 2575 valves only